ANNEX 6

GENERIC SPECIFICATIONS FOR X-RAY AND ULTRASOUND UNITS

1. Stationary X-ray units

The major requirements for any stationary X-ray unit are as follows:

(i) Medium or high frequency converter with a tube generating potential (voltage) range of 45-120 kV.

Note: Some type of power storage may be required, e.g., a capacitor or battery (see below). A generator with falling tube current (mA) during exposure is preferable to one with constant tube current.

(ii) Minimum power, 11kW (at 0.1 s); minimum available energy, 25 kWs.

Note: If the relative speed of the screen-film system is 400, the energy requirement may be reduced to 12kWs. The power requirement remains the same.

(iii) Focal spot size, 1 mm or less.

(iv) Accurate, variable collimator, which cannot be removed.

(v) Minimum focus-film distance, 100 cm for vertical-beam radiography; 140 cm for chest radiography with horizontal beam.

It should be noted that single-phase two-pulse generators (not involving multi-pulse converter technology) and capacitor discharge units without constant voltage (kV) during exposure are not recommended.

2. General-purpose ultrasound scanner

(1) *Transducer*

Standard unit: 3.5 Mhz centre frequency.

Optional unit: 5.0 Mhz centre frequency.

Fixed in-slice focusing on both units desirable but not essential.

Sector angle 400 (sector scanner) or better.

Array length: 58 cm (linear array scanner).

(2) *Controls*

To be simple and clearly arranged.

Gain control is required.

Time gain compensation to be by choice of present and variable conditions.

(3) *Frame rate*

5-10 Hz (sector scanner), 15-30 Hz (linear array scanner).

(4) *Frame freeze and display*

512 x 512 x 4 bits (to provide 16 "grey" levels).

(5) *Omnidirectional callipers*

One pair to be provided, with facility for quantitative read-out and recording.

(6) *Patient identification*

Facilities to be provided for manually entering and recording data-patient identification, date, etc.-on the image screen.

(7) *Permanent recording*

Provision must be made for the economical preparation of good-quality permanent image records.

(8) *Construction*

The unit should be portable (not more than 8 kg), drip-proof, and dust-proof. Proper and continuous operation should be possible under the following conditions:

Temperature:	0°C to + 40°C.
Humidity:	up to 95%.

Prolonged storage should be possible under the following conditions:

Temperature:	-30°C to +50°C.
Humidity:	up to 100%.

The unit should be rugged and capable of withstanding the vibration likely to occur during rough, cross-country transport. Special care should be taken to avoid failure of the transducer, its cable, and its connector under the above conditions. The mechanical design of the transducer should include:

(a) Maximum protection against damage by dropping;

(b) Tolerance of the use of a variety of coupling media, particularly local vegetable oils.

(9) *Electrical and mechanical safety*

This equipment should conform to the standards set out by the International Electrotechnical Commission (Medical Electrical Equipment)[1]. Where interventional use is intended, particular care must be taken to ensure that the relevant standards of equipment earthing (grounding) and leakage of current are met.

(10) *Power supply*

The equipment must be capable of working from any of the following types of supply:

Direct current: standard batteries, preferably rechargeable.

Alternating current:

- 50 and 60 Hz

- 00,110, 117,125 and 200,220,240 V.

- line voltage variation + 15%.

Surge protection to be provided.

(11) *Servicing* and *quality control*

Although modern equipment should be reliable and stable in performance, both failures and degradation should be anticipated; the following quality control procedures are highly recommended:

(a) At regular intervals (at least every 3 months and preferably every week) the resolution and sensitivity performance of the unit should be checked using a suitable phantom. Corrections should be made if there is any appreciable change in performance over a period of time.

(b) Arrangements should be made (with the manufacturer or otherwise) for a centralized repair and maintenance service to be provided, to cover a number of units in a country or region.

(c) Provision must be made for a supply of spare parts to be rapidly available. These parts must include spares for the transducer, the display monitors, and the principal electronic assemblies.

(12) Space

Ultrasound examinations may be made at the bedside, but it is preferable to set aside a room that will provide both privacy (if necessary by curtains) and a suitable horizontal support for the patient. It is helpful if the room illumination can be reduced. A toilet should be provided close to this room. In busy departments the provision of several changing cubicles with increase the number of patient examinations that can be carried out. No added structural protection is required.

[1] *General requirements.* Geneva, International Electrotechnical Commission, 1977 (Publication No. 601-1). *Particular requirements for specific types of equipment (including ultrasound and computed tomography).* Geneva, International Electrotechnical Commission (in preparation) Publication No.601-2).

ANNEX 7

OPTIONAL MEDICAL IMAGING EQUIPMENT

1. Mobile X-ray units

If a mobile X-ray unit is purchased, the power source can be batteries (preferred) or mains. A battery-powered unit needs a mains connection only when the batteries are being charged. Most battery-powered mobile units can deliver 10-12 kW for at least 2.5 s, resulting in a total energy output of 25-30 kWs.

A mains-connected mobile unit must contain a built-in capacitor to reach the output needed. Capacitor discharge (also known as condenser discharge) X-ray units store enough energy for a single X-ray exposure. They must be connected to a power source during operation for recharging, but this source can be a standard grounded wall outlet. The capacitor may be connected on the primary (low-voltage) side or on the secondary (high-voltage) side of the high-voltage transformer.

Connection on the secondary side is usually combined with constant X-ray tube current (mA), resulting in failing kV during the exposure. Such a unit can be used to X-ray the chest and the extremities only and should not be purchased for general purpose radiography.

Connection of the capacitor on the primary side of the transformer is usually combined with a multipulse converter circuit with falling mA but constant kV during the exposure. This is a very good technical solution, often resulting in high initial power output (20-30 kW) and a satisfactory total energy output of about 10 kWs.

Do not purchase a mobile unit that requires special high-power wall outlets to function. This rules out use of all two-purse single-phase units.

As already noted [para (a) (1)], a mobile unit is not essential in many small hospitals but may be needed for orthopaedic surgery .Almost all other immobilized patients are better taken to the X-ray department for examination on their beds.

2. Fluoroscopic equipment

WHO does not recommend the purchase of fluoroscopic equipment, even with image intensification, unless a specialist radiologist is present to use it. As stated in WHO Technical Report Series No. 689, *A Rational Approach to Radio diagnostic Investigations* (section 4.2), " A general and important recommendation is that all barium studies should be carried out only by qualified radiologists using appropriate fluoroscopic equipment.

There are several reasons for this recommendation :

(i) Over 90%, often 95%, of all the imaging required in 50-100-bed first-referral hospitals is of the chest and skeleton. Radiography of the abdomen, gall-bladder and urinary tract accounts for most of the other needs. None of these examinations requires fluoroscopy. In particular, WHO strongly recommends that chest fluoroscopy be replaced by radiography (a chest film) (WHO Technical Report Series No. 689, section 2.3.8).

(ii) The initial cost of fluoroscopy equipment and the recurring costs are considerable and not cost-effective.

(iii) The radiation dose delivered during fluoroscopy is high.

(iv) The diagnostic accuracy of fluoroscopy is very low. In particular, "routine" chest fluoroscopy is never indicated as part of a medical examination (WHO Technical Report Series No. 689, sections 2.1.5 and 2.3.8).

(v) Ultrasound adds considerably to the diagnosis of abdominal problems and involves no exposure to radiation.

(vi) Gastrointestinal examinations should be performed only by specialist radiologists.

3. Recording the ultrasound image

If the physicians are conscientious, the results of an ultrasound examination, including measurements, can simply be written in the patient's records, without an accompanying image. If affordable, however, a permanent image is preferable. A permanent record of the image can be obtained in several ways, which vary in expense and efficiency; all require additional attachments:

(i) The least expensive is to record on special paper. At present, the resulting image is not of very good quality.

(ii) Recording on Polaroid® film requires a special camera which photographs the video image. This method is quick and efficient, but the film is expensive and not always available.

(iii) Recording on X-ray film requires a separate recorder, which produces an excellent image after the film has been processed in the X-ray darkroom. The recorder is expensive.

Careful discussions should be held with the medical staff and the company that will supply the equipment in order to clarify the needs, the initial cost and the recurring costs.